Amended claims to be filed with the USPTO

CLAIMS

What is claimed is:

1. A stabilized lyophilized hepatitis A live vaccine formulation comprising a prophylactically effective titers of live attenuated hepatitis A virus and a stabilizer, wherein said stabilizer being present in the vaccne formulation at a concentration sufficient to stabilizer the hepatitis A virus against heat inactivation.

2. A stabilized lyophilized hepatitis A live vaccine formulation according to claim 1, wherein said live attenuated hepatitis A virus is prepared by disclosed method based on the wide-type HAV, stain L-A-I.

3. A stabilized lyophilized hepatitis A live vaccine formulation according to claim 1, wherein said stabilizer for lyophilized live hepatitis A virus composed of gelatin, trehalose, one or two animo acid selected from the group consisting of glutamic acid, aspartic acid, arginine, lysine or alkali metal salts thereof, ascorbic acid, urea, mannitol or sorbitol or a mixture of them, and inositol.

4. A stabilized lyophilized hepatitis A live vaccine formulation according to claim 1, wherein said stabilizer for lyophilized live virus vaccine may optionally contains human serum albumin.

5. A stabilized lyophilized hepatitis A live vaccine formulation according to claim 1, wherein said stabilizer for the lyophilized live virus essentially composed of from 0 to 20 grams per liter of human serum albumin, from 5 to 10 grams per liter of gelatin, from 50 to 100 grams per liter of trehalose, from 7.5 to 15 grams per liter of sodium glutamate, from 0.5 to 5.5 grams per liter of ascorbic acid, from 5 to 28 grams per liter of urea, from 2 to 10 grams per liter of mannitol or sorbitol,

and from 4 to 10 grams per liter of inositol .

6. A method of preparing stabilized lyophilized live hepatitis A vaccine formulation according to any one of the claims 1 to 5, comprising:

(a) providing a stock suspension of attenuated live Hepatitis A virus;

(b) adding a stabilizer solution to a stock suspension of attenuated live hepatitis A virus obtained from step (a) at the ratio 1:1(v/v) to obtain a live vaccine formulation comprising prophylactically effective titers of live attenuated hepatitis A virus and a stabilizer for attenuated live virus, wherein said stabilizer comprises gelatin, thehalose, one or two amino acid selected from the group consisting of glutamic acid, asparitc acid, arginine, lysine or alkali metal salts thereof, ascorhic acid, urea, mannitol or sorbitol or a mixture of them, and inositol.

(c) lyophilizing said vaccine formulation obtained from the step (b).

7. A stabilizer for lyophilized live virus, wherein said stabilizer essentially composed of gelatin, trehalose, one or two amino acid selected from the group consisting of glutamic acid, aspartic acid, arginine, lysine or alkali metal salts thereof, ascorbic acid, urea, mannitol or sorbitol or a mixture of them, and inositol.

8. A stabilizer according to claim 7, wherein said stabilizer essentially composed of from 0 to 20 grams per titer of human serum albumin, from 5 to 10 grams per liter of gelatin, from 50 to 100 grams per liter of trehalose, from 7.5 to 15 grams per liter of sodium glutamate, from 0.5 to 5.5 grams per liter of ascorbic acid, from 5 to 28 grams per liter of urea, from 2 to 10 grams per liter of mannitol or sorbital, and from 4 to 10 grams per liter of inositol.

9. A stabilizer according to claim 7, wherein said stabilizer for

lyophilized live virus vaccine may optionally contains human serum albumin.

10. A stabilizer according to claim 7, wherein said stabilizer not only suitable for stabilizing lyophilized hepatitis A live virus, but also used for protecting viruses selected from the group consisting of the genus Enterovirus, the genres Papamyovirus, the genus Arbovirus, and the genus Herpevirus against heat inactivation during the period of lyophilization and the period of storage and transportation post-lyophilization to ensure thermo-stability of the lyophilized live vaccine thereby to improve vaculation efficacy for susceptible population.